

# Lombard Medical's Aorfix™ Receives Regulatory Approval in Japan for Treatment of Abdominal Aortic Aneurysms

Experienced Japanese Distributor, Medico's Hirata, to Launch Device Imminently

Japan is Second Largest, Standalone Endovascular Aneurysm Repair Market

Irvine, CA and London, UK – August 5, 2014 – Lombard Medical, Inc. (NASDAQ: EVAR), a medical device company focused on Endovascular Aneurysm Repair (EVAR) of abdominal aortic aneurysms (AAA), today announced that its lead product, Aorfix™, an endovascular stent graft to treat AAA, has received approval from the Japanese Ministry of Health, Labour and Welfare. Commercial sales will follow reimbursement approval, which the Company anticipates receiving in September. Aorfix will be exclusively distributed by Medico's Hirata Inc., one of Japan's leading suppliers of vascular products with proven expertise in building significant market share for AAA stent grafts. Japan is the world's second largest, standalone EVAR market.

Aorfix is the first and only endovascular stent graft approved in Japan to treat AAA in patients with aortic neck angulations up to 90 degrees, commonly considered to be challenging cases. Aorfix is currently approved to treat patients with neck angles up to 90 degrees in the US and Europe.

Lombard Medical's CEO Simon Hubbert commented, "Japan is a substantial EVAR market – both strategically and financially - and the approval of Aorfix is a significant milestone for the Company. We are confident that, through Medico's Hirata's experienced and established sales force, we will be able to realize the full potential of Aorfix in this growing market. We look forward to providing Japanese physicians with our uniquely differentiated stent graft approved to address the significant population of patients with complex anatomies who, until today, had no 'on-label' minimally invasive treatment option."

Masataka Hirata, President of Medico's Hirata Inc., said, "This approval of Aorfix allows us to provide physicians with a new, minimally invasive treatment option for Japanese patients with challenging AAAs. These physicians would otherwise have had to choose between taking responsibility for attempting treatment with a stent graft not specifically approved for more complex AAA anatomies, or resorting to open surgery, which is more invasive and, typically, carries higher associated risks."

The EVAR market in Japan is estimated at \$140 million or 10% of the global market in 2013, and has been growing at an average rate of 18% over the last five years. In Japan, there are approximately 400 physicians at 200 clinics performing EVAR and it is estimated that approximately 55% of Japanese AAA patients are treated using this method.<sup>1</sup>

### **About Abdominal Aortic Aneurysms (AAAs)**

AAAs are balloon-like enlargements of the aorta which, if left untreated, may rupture and cause death. Approximately 4.5 million people are living with AAAs in the developed world and each year over 500,000 new cases are diagnosed. In the US, aortic aneurysm disease is among the leading causes of death and it is estimated that 1.5 million people have an abdominal aortic aneurysm.

## **About Medico's Hirata**

Founded in 1918 and headquartered in Osaka, Medico's Hirata Inc. is a leading supplier and developer of medical device products for the Japanese healthcare industry. With more than 100 devices approved, the Company has built up extensive industry experience and a thorough understanding of the regulatory landscape in Japan. In 2006 the Company received regulatory approval to launch aortic stent grafts for the treatment of abdominal aortic aneurysms ("AAAs"), complementing its broad portfolio of minimally invasive, innovative devices in the field of vascular intervention.

Further background on the Company can be found at http://www.medicos-hirata.co.jp/english/.

## **About Lombard Medical, Inc.**

Lombard Medical, Inc. is a medical device company focused on device solutions for the \$1.4 billion per annum abdominal aortic aneurysm repair market. The Company's lead product, Aorfix™, is an endovascular stent graft which has been specifically designed to solve the problems that exist in treating complex tortuous

anatomy, which is often present in advanced AAA disease. Lombard Medical, Inc. is based in Oxfordshire, England with US commercial headquarters in Irvine, CA and is registered in the Cayman Islands.

Further background on the Company can be found at www.lombardmedical.com.

#### FORWARD-LOOKING STATEMENTS

This announcement may contain forward-looking statements that reflect the Company's current expectations regarding future events, including the commercialization and additional regulatory clearances of the Company's products, the Company's liquidity and results of operations, as well as future capital raising activities. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including the success of the Company's research and development and commercialization strategies, the uncertainties related to the regulatory process and the acceptance of the Company's products by hospitals and other medical professionals and the risks, uncertainties and other factors described under the heading "Risk Factors" in the Company's prospectus filed with the Securities and Exchange Commission dated April 25, 2014. The Company undertakes no obligation to update these statements in the future.

#### For further information:

Lombard Medical. Inc.

Simon Hubbert, Chief Executive Officer Tel: +1 949 379 3750 / +44 (0)1235 750 800

Ian Ardill, Chief Financial Officer Tel: +44 (0)1235 750 800

**Pure Communications** 

Matthew H Clawson Tel: +1 949 370 8500 / matt@purecommunicationsinc.com

FTI Consulting (UK)

Simon Conway, Victoria Foster Mitchell Tel: +44 (0)20 3727 1000

<sup>1</sup> Medtech Ventures: Aortic Intervention Market (2014)